K100716

Aalto Scientific, Ltd.

510(k) Notification
Audit™ MicroCV™ D-Dimer Linearity Set

JUN 23 2011

510(k) Summary

A. Submitter

Aalto Scientific, Ltd.
1959 Kellogg Ave.
Carlsbad, CA 92008
Telephone: (760) 431-7922
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B. Contact Person

Dessi Lyakov
Regulatory Affairs Manager
Telephone: (760) 431-7922 Ext. 118
E-mail: dlyakov@aaltoscientific.com

C. Date of Summary Preparation

June 9, 2011

D. Device Identification

Product Trade Name:	Audit™ MicroCV™ D-Dimer Linearity Set
Common Name:	D-Dimer Linearity
Classification Name:	Plasma, Coagulation Control
Device Classification:	Class II
Regulation Number:	21 CFR 864.5425
Panel:	81 Hematology
Product Code:	GGN

E. Device to Which Substantial Equivalence is Claimed

Product Trade Name:	Triage® D-Dimer Calibration Verification Controls Biosite Incorporated, San Diego, CA 92121 K050799

F. Description of the Device

The Audit™ MicroCV™ D-Dimer Linearity Set is a human based, lyophilized, five level set of QC material, with each level containing D-Dimer complex. It is used to confirm the proper calibration, linear operating range, and reportable range of D-Dimer complex. Level A is near the lower limit level and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E.

G. Statement of Intended Use

The Audit™ MicroCV™ D-Dimer Linearity Set is a quantitative, assayed quality control material consisting of five levels of D-dimer analyte. The five D-dimer levels demonstrate a linear relationship to each other for D-dimer analyte. The Audit™ MicroCV™ D-Dimer Linearity Set is intended to use with the Biomerieux miniVIDAS® analyzer and VIDAS® D-dimer assay to verify the calibration of the measuring range.Audit™ MicroCV™ D-Dimer Linearity Set is "For *In Vitro* Diagnostic Use Only."

I. Summary of Performance Data

Stability studies have been performed to determine the reconstituted stability and shelf life for the Audit™ MicroCV™ D-Dimer Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Reconstituted Stability: Once a vial has been reconstituted, all analytes will be stable for 2 days when stored tightly capped at 2 - 8° C.

Shelf Life: Two Year, when stored unopened at 2 - 8° C.

Note: Real time studies are ongoing to support the shelf life of this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Aalto Scientific, Ltd.
c/o Mr. Brandon Perez
Regulatory Affairs Specialist
1959 Kellogg Ave.
Carlsbad, CA 92008

JUN 23 2011

Re: k100716
Trade/Device Name: Audit™ MicroCV™ D-Dimer Linearity Set
Regulation Number: 21 CFR 864.5425
Regulation Name: Plasma, Coagulation Control
Regulatory Class: Class II
Product Code: GGN
Dated: June 9, 2011
Received: June 10, 2011

Dear Mr. Perez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Aalto Scientific, Ltd.

510(k) Notification
Audit™ MicroCV™ D-Dimer Linearity Set

Indications for Use

510(k) Number: K100716

Device Name: Audit™ MicroCV™ D-Dimer Linearity Set

Indications For Use:

The Audit™ MicroCV™ D-Dimer Linearity Set is a quantitative, assayed quality control material consisting of five levels of D-dimer analyte. The five D-dimer levels demonstrate a linear relationship to each other for D-dimer analyte. The Audit™ MicroCV™ D-Dimer Linearity Set is intended to use with the Biomerieux miniVIDAS® analyzer and VIDAS® D-dimer assay to verify the calibration of the measuring range.Audit™ MicroCV™ D-Dimer Linearity Set is "For *In Vitro* Diagnostic Use Only."

Prescription Use ___X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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